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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,019	09/10/1999	AKIRA KOMORIYA	3273.002US1	3625

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/394,019

Applicant(s)

KOMORIYA ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 27,30.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-15 are pending.

Applicant's amendment filed March 17, 2003 (Paper No. 29) is acknowledged, and applicants' response has been fully considered. Claims 16-26 have been cancelled, and claims 1, 4 and 6 have been amended. Therefore, claims 1-15 and SEQ ID NOs:212 and 248 are examined.

2. Figs 4A, 4B and 5 have been submitted in Paper No. 29, however, the drawings have been objected, please see attached PTO-948.

### **Objection Withdrawn**

3. The previous objection to the specification is withdrawn in view of applicant's amendment to the specification and applicant's response at page 5 in Paper No. 29.
4. The previous objection to claims 1 and 4 is withdrawn in view of applicant's amendment to the claim and applicant's response at page 5 to the claim in Paper No. 29.

### **Rejection Withdrawn**

### ***Claim Rejections - 35 USC § 112***

5. The previous rejection of claims 1-15, under 35 U.S.C.112, second paragraph, regarding the recitation of non-elected sequences in the claim, or, the term "dipeptide", "fm and fmoc", "between about", "or other anion", "bears a hydrophobic group", is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 5 in Paper No. 29.

### ***Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5-13 of U. S. Patent 6,037,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-15 in the instant application disclose a fluorogenic composition for the detection of the activity of a protease having the formula cited in claim 1, where P is a peptide having a sequence such as LEHDGIN, F<sup>1</sup> and F<sup>2</sup> are fluorophores, S<sup>1</sup> and S<sup>2</sup> are spacers, aa<sup>1</sup>, aa<sup>10</sup>, aa<sup>2</sup>, aa<sup>3</sup>, aa<sup>8</sup>, aa<sup>9</sup>, aa<sup>5</sup>, aa<sup>4</sup>, aa<sup>6</sup>, aa<sup>7</sup>, X and Y are defined in the claim. This is obvious in view of claims 1 and 5-13 in the patent which disclose a fluorogenic composition for the detection of the activity of a protease having the formula cited in claim 1, where P is a peptide comprising a protease binding site for the protease, F<sup>1</sup> and F<sup>2</sup> are fluorophores, S<sup>1</sup> and S<sup>2</sup> are spacers, aa<sup>1</sup>, aa<sup>10</sup>, aa<sup>2</sup>, aa<sup>3</sup>, aa<sup>8</sup>, aa<sup>9</sup>, aa<sup>5</sup>, aa<sup>4</sup>, aa<sup>6</sup>, aa<sup>7</sup>, X and Y are defined in the claim. Both sets of claims cite a fluorogenic composition for the detection of the activity of a protease having the formula, wherein P is a peptide comprising a protease binding site for the protease such as LEHDGIN. Thus, claims 1-15 in present application and claims 1 and 5-13 in the patent are obvious variations of a fluorogenic composition for the detection of the activity of a protease, which contains a peptide having a protease binding site such as LEHDGIN.

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In response, applicants indicate they will provide a Terminal Disclaimer upon indication of patentable subject matter. The comment is unpersuasive. The ground of rejection remains. No allowable material can be indicated when a ground of rejection remains.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-15 are indefinite because the claim recites an amino acid "Nlu" in the amino acid sequences for SEQ ID NOs:212 and 248, it is not clear what Nlu is. In the sequence listing, SEQ ID NOs:212 and 248 have Asn in the corresponding position. Claims 2-15 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend. See 37 CFR 1.821-1.825 and MPEP Chapter 2400, Section 2422, Table 4, which lists appropriate abbreviations.

8. Claim 4 is indefinite because the claim recites Lys-Asp-Pro-Ahx-Gly-Leu-Glu-His-Asp-Gly-Ile-Asn-Gly-Ahx-Pro-Lys-Gly-Tyr (SEQ ID NO:248), which does not conform the formula of claim 1 (see paragraph 7 of the previous Office Action, Paper No. 26). Claim 1 indicates  $aa^2$ ,  $aa^3$ ,  $aa^8$  or  $aa^9$  is an amino acid, and according to the formula,  $(aa^2-aa^3)_k$  is either a dipeptide or no amino acid residue depending on k being 0 or 1. However, SEQ ID NO:248 (or other sequences in Tables 3 and 4) has Asp as  $(aa^2-aa^3)$ .

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***Conclusion***

9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Chih-Min Kam, Ph. D.  
Patent Examiner

CMK



CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
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July 1, 2003